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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,587	11/28/2000	Jean Francois Bloch	746220.0003 (58763.000003)	6164
21967	7590	01/28/2004	EXAMINER	
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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012104

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Commissioner for Patents

--See attached--

Office Action Summary

Application No.

09/722,587

Applicant(s)

BLOCH ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 and 12-32 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-6, 12, 13, 15, 18, 20, 23, 25 and 30-32 is/are allowed.
- 6) ☒ Claim(s) 14, 16, 17, 21, 22, 24 and 26-28 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claim 29 stands withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election **without** traverse was confirmed in the paper filed 3 November 2003.

Claims 2-6, 12, 13, 15, 18, 20, 23, 25 and 30-32 are allowed.

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not apparent that claim 18 differs in scope from instant claim 19.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by the 1991 GIBCO BRL Supplement and Price List (“GIBCO”, designated as reference U, newly cited).

The instant claim is drawn to a support with a series of sites for the implementation of the method of claim 2, wherein each one of said sites permits the detection and/or the measurement of a variation of function.

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GIBCO teaches, e.g., at page 736, under “Cell Culture Cluster Dishes” at the left-hand column, or in the right-hand column under “Microtitration Plates”, several types of multi-well dishes or plate, which would serve to contain a set or series of reactions such as those recited in claim 2. The phrase “each one of said sites permits the detection and/or the measurement of a variation of function” is not understood to be limited to the presence of reaction reagents and materials in each site on the support, i.e., each well of the plate or dish. Rather, the plate or dish itself meets the limitations of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 17 recites “wherein said proteins are variants of a protein or variants of a collection of proteins.” However, the genus encompassing all possible variants of all proteins that might be employed in the invention of the instant claims is vast. There is no algorithm or formula in the art which would have permitted one of skill to have known which variants of any particular protein retained the function or activity of that protein, in view of the incomplete

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nature of the understanding of protein structure-function relationships. Certainly, for such a vast genus, Applicants have not presented a representative sample of protein variants to demonstrate to one of skill in the art that Applicants were in possession of the full scope of the claimed invention at the time of filing. As such, an adequate written description of the claimed invention is not present.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16, 17, 21, 22, 24, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase “or from a phylogenetically close organism.” However, the term “close”, in the absence of a precise definition, is a relative term. As such, the degree of closeness is unspecified, and thus the metes and bounds of the instant claim are indefinite.

Claim 16, at line 2, recites the term “can be”. However, as a result, it is not clear that either subsequently set forth alternative, “natural site” or “another ribosome binding site”, must be present, i.e., is this list of two alternatives exhaustive, or does another genus of embodiments exist within the scope of the claim? It is suggested that the term “is” be substituted.

Further in respect of claim 16, at line 3, the term “more adapted” is unclear. What properties are conveyed by this term? Higher binding affinity? Lower binding affinity? This term renders the metes and bounds of the claim indefinite.

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In claim 17 and dependent claim 22, the twice-used term “variants” is unclear. The extent to which the sequence of the protein (or proteins) has (or have) been varied is not defined. For example, would variation of the sequence such that every amino acid were altered, to regenerate a completely different protein, be encompassed? If so, it then becomes unclear what limitation this term actually imposes on the instant claim, which itself renders indefinite the metes and bounds of the claim.

In claim 21, line 4, the term “similar to” is a term of degree, and in the absence of a precise definition, renders indefinite the metes and bounds of the claim.

In claim 24, the term “substance” refers to, among others, “physico-chemical conditions, radiation, or thermal treatments.” However, these three entities are not substances, thus rendering the meaning of the claim confusing.

Claim 26, and dependent claim 27, recite “to the transcription and to the translation.” However, the preposition “to” in each instance is confusing, and as a result, it is not clear what grammatical part of the claim these prepositional phrases modify. If “for” was intended, modifying “preparation”, this substitution should be made, and it is further suggested that the comma before the first “to” be deleted, as well.

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-

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9306 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
January 21, 2004



JAMES KETTER
PRIMARY EXAMINER